

**REMARKS/ ARGUMENTS**

Favorable reconsideration of this application is requested in view of the amendments above and the remarks which follow.

Claims 1-9 and 13-15 are pending in this application. Claims 10-12 and 22-26 have been withdrawn due to a restriction requirement. Claims 16-21 have been cancelled.

**Rejections under 35 U.S.C. §102**

Claims 1-2, 4, 5, 6, 13, and 15 were rejected under 35 U.S.C. §102(b) as being anticipated by Ayer (GB 2,174,299). Reconsideration of this rejection is respectfully requested.

A problem encountered with the formation of exit orifices by laser drilling is the imprecise control of the depth of penetration by the laser beam. On the one hand, the laser beam must penetrate the outer wall to a depth sufficient to provide an exit orifice for operation of the device. On the other hand, it is undesirable for the laser beam to penetrate to a significant extent beyond the outer wall. For solid dosage forms, penetration of the laser beam beyond the depth of the outer wall may result in loss of some core material from the internal compartment. For liquid dosage forms, penetration of the laser beam beyond the depth of the outer wall may result in piercing of the capsule wall, resulting in unacceptable leakage of the liquid contents from the dosage form.

Amended claim 1 recites a dosage form comprising an outer wall defining an interior compartment, a therapeutic agent within the interior compartment, at least one laser formed exit orifice in the outer wall, and a barrier layer disposed between the outer wall and interior compartment in at least a region corresponding to the at least one exit orifice. The barrier layer comprises a material that allows the barrier layer to remain intact during formation of the exit orifice. The material is present in the barrier layer in an amount sufficient to make the barrier layer substantially impervious to laser ablation under a selected laser type and selected laser operating conditions used to form the exit orifice. Advantageously, this allows the barrier layer to act as an endpoint for laser ablation during formation of the exit orifice in the outer wall, preventing unintended removal of material from the dosage form.

Ayer discloses a hydrogel layer in an interior compartment of a dosage form. The Examiner likens the hydrogel layer to the barrier layer of the present invention. However, Ayer

does not disclose or teach that the hydrogel layer is substantially impervious to laser ablation. What Ayer teaches is that the hydrogel layer includes means (17) that exhibits the ability to flow and form a film under the influence of laser energy. The idea is to allow means (17) to flow into a passageway formed in the dosage form and seal the passageway. In order for means (17) to be able to flow and form a film under the influence of laser energy, means (17) would have to be able to absorb the laser energy and would therefore not be substantially impervious to laser ablation. Ayer does not disclose or teach the presence of any material in the hydrogel layer in a sufficient amount to make the hydrogel layer substantially impervious to laser ablation. Further, Ayer teaches that means (17) flows into the passageway drilled in the dosage form. Therefore, the hydrogel layer containing means (17) cannot be considered as remaining intact during formation of the passageway.

From the foregoing, Ayer does not anticipate or make obvious the invention recited in amended claim 1. Withdrawal of the rejection of claim 1 over Ayer is respectfully requested. Claims 2, 4, 5, 6, 13, and 15, being dependent on claim 1, are likewise patentable in view of the foregoing arguments.

#### **Rejections under 35 U.S.C. §103**

Claims 1-6, 13, and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ayer in view of Ayer et al. (U.S. Patent No. 4,285,987) and Theeuwes et al. (U.S. Patent No. 4,088,864). Reconsideration of this rejection is respectfully requested.

As previously discussed, Ayer does not disclose or teach a barrier layer comprising a material that allows the barrier layer to remain intact during formation of the exit orifice and that is present in an amount sufficient to make the barrier layer substantially impervious to laser ablation under a selected laser and selected laser operating conditions used to form the exit orifice, as recited in claim 1. Ayer et al. and Theeuwes et al. also fail to overcome the deficiency in Ayer. Therefore, Ayer combined with Ayer et al. and Theeuwes et al. cannot render claim 1 obvious. Withdrawal of the rejection of claim 1 is respectfully requested. Claims 2-6, 13, and 15, being dependent on claim 1, are likewise patentable in view of the foregoing arguments.

**Allowable Claims**

Claims 7-9 and 14 were objected to as being dependent on rejected independent claims. Claims 7 and 14 have been rewritten in independent form, including limitations of the base claim and any intervening claims. Claims 8 and 9 depend from claim 7. Withdrawal of the objection to claims 7-9 and 14 is respectfully requested.

**Conclusion**

The rejected claims have been amended and/or shown to be allowable over the prior art. Applicant believes that this paper is fully responsive to each and every ground of rejection cited by the Examiner in the Office Action dated February 26, 2003, and respectfully request that a timely Notice of Allowance be issued in this case.

Please apply any charges not covered or any credits to Deposit Account 10-0750 (Johnson & Johnson).

Respectfully submitted,

Date: 3/30/2004

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